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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,972	06/15/2000	Ada Goerlach-Graw	BMID 9941 US	8671

32842 7590 06/17/2004

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/594,972	GOERLACH-GRAW ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

1. Applicant's amendment filed 4/14/2004 has been received. Claims 1-14 and 27-42 have been cancelled. Claims 15-26 are pending.

2. All rejections not reiterated herein below are withdrawn.

3. The text of those US codes not found in this office action may be found in a previous office action.

Claim Rejections - 35 USC § 112

4. Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is vague because it is unclear what reagents, if any, are in the detection zone that would enable it to detect the analyte.

Response to Arguments

5. Applicant's arguments filed 4/14/2004 have been fully considered but they are not persuasive.

Applicant argues that claim 15 does not recite reagents in the detection zone, because no reagents beyond those already recited in the claim for detecting the analyte are required. Applicant argues that when analyte is present, a complex between the analyte, first bioaffine binding partner and second bioaffine binding partner with a direct visual detectable label is formed, and because both binding partner can be detached from the matrix material by liquid,

the analyte to be determined is conjugated with a visually detectable label with it reaches the detection zone thus allowing detection.

This argument has been fully considered, and while it is true that in the present of analyte, a visually detectable complex forms and migrates to the detection zone, however, without any reagents or other impediments in the detection zone to inhibit further migration, the complex will continue to travel pass the detection zone thus resulting in no detection. Further clarification is required.

Claim Rejections - 35 USC § 103

6. Claims 15-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick et al (US 5,451,504) in view of Decker et al (US 4,230,683) for reasons of record which are reiterated herein below.

Fitzpatrick discloses a device and method for detecting the presence and amount of an analyte in a sample. The device of Fitzpatrick comprises a chromatographic strip having a sample contact zone, a trapping zone, and a detection zone. The sample contact zone contains mobilizable, labeled-receptor to the analyte. The trapping zone contains immobilized ligand (analyte or analyte analog) that will bind free receptor moving through the trap zone. And, the detection zone contains immobilized receptor that will bind the labeled-receptor/analyte complex enabling their detection therein. See columns 4-9 and figure 1. Fitzpatrick teaches labels such as colloidal gold or colored latex particles for use in the device. See column 8, lines 30-48.

Fitzpatrick differs from the claimed invention in failing to teach a universal conjugate.

Decker, however, teaches an improved method for detecting antigen by reacting a hapten-labeled antibody with the antigen, and then reacting the hapten moiety with a second, labeled anti-hapten antibody, and determining the amount of label bound to a solid support as a measure of the amount of the antigen in a sample. Decker teaches haptens such as digoxin as appropriate for use in the hapten-labeled antibody. See column 1, lines 19-32, and lines 55-68. Decker teaches that the hapten-labeled antibody provides the advantages of amplifying the antigenicity of the bound antibody, thus, enabling an increased in binding of the antibody to the antigen. See column 2, line 34 through column 3, line 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Fitzpatrick by using the hapten-labeled method of Decker. Such a modification provides the advantage of amplifying the antigenicity of the bound antibody thereby increasing the sensitivity of the assay as taught by Decker. Further, a skilled artisan would have had a reasonable expectation of success in using the hapten-labeled antibody of Decker in the device of Fitzpatrick because such modification is a mere alternative and functionally equivalent labeling technique that is well known in the art. See Decker, column 1, lines 5-32. Additionally, since only the expected labeling effect would have been obtained, the use of alternative and functionally equivalent labeling techniques, such as taught by Decker, would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

7. Claims 18, 19 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzpatrick in view of Decker as applied to claims 15-17 and 20-23 above, and further in view of Bernstein et al (US 5,824,268) for reasons of record which are reiterated herein below.

See the discussion of Fitzpatrick and Decker above. These references differ from the claimed invention in failing to teach an elution agent application zone located upstream of the sample application zone.

Bernstein, however, discloses a test device comprising a series of bibulous strips having a buffer zone, a sample zone, a reaction zone and a detection reagent zone, consecutively (column 6, lines 24-67). Bernstein teaches that the disclosed device provides the advantages of a simple test device where all the reagents, including liquid phase solvents, buffers, etc, necessary to perform the assay are incorporated and requiring only the additional of test sample. The placement of the various zones allows the appropriate addition of reagents and improves the assay results because the presence of the analyte can be determined in a sequential form of immunoassay. And, because all reagents are flowing simultaneously, the assay time will be shorter for any given result.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device of Fitzpatrick as modified by Decker to include a buffer addition zone upstream of the sample addition zone such as taught by Bernstein. The inclusion of such a buffer addition zone provides the advantages of a simple test device where all the reagents, including liquid phase solvents, buffers, etc, necessary to perform the assay are incorporated and requiring only the additional of test sample. Further, Bernstein teaches that the placement of the various zones allows the appropriate addition of reagents and improves the assay results because the presence of the analyte can be determined in a sequential form of immunoassay. And, because all reagents are flowing simultaneously, the assay time will be shorter for any given result.

A skilled artisan would have had a reasonable expectation of success in modifying the device of Fitzpatrick to include a buffer addition zone as taught by Bernstein because Fitzpatrick teaches that more than three zones may be included in it's device (Fitzpatrick, column 3, lines 27-37), and Bernstein teaches that it is advantageous to include all reagents necessary for an assay in one test device (Bernstein, column 3, lines 28-38).

Response to Arguments

8. Applicant's arguments filed 4/14/2004 have been fully considered but they are not persuasive.

Applicant argues that Fitzpatrick fails to teach in their list of labels a low molecular organic molecule as its label. Specifically, Fitzpatrick does not disclose a first conjugate that binds analyte which has a low molecular organic molecule as its label.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Fitzpatrick is cited for their general teaching of an element comprising a sample application zone, a zone containing labeled binding partner for the analyte, a trap zone containing immobilized analyte and a detection zone.

Decker teaches the universal conjugate system.

Because Fitzpatrick specifically teaches that the choice of detection means can be made on the basis of convenience of the practitioner. Various detection means known in the art fall within the scope of the invention taught by Fitzpatrick (column 8, lines 54-57). And because

Decker teaches an improvement in immunoassay using a universal conjugate system, a skilled artisan would have been motivated to modify the device of Fitzpatrick by using the hapten-labeled method of Decker. Such a modification provides the advantage of amplifying the antigenicity of the bound antibody thereby increasing the sensitivity of the assay as taught by Decker. Further, a skilled artisan would have had a reasonable expectation of success in using the hapten-labeled antibody of Decker in the device of Fitzpatrick because such modification is a mere alternative and functionally equivalent labeling technique that is well known in the art. See Decker, column 1, lines 5-32. Additionally, since only the expected labeling effect would have been obtained, the use of alternative and functionally equivalent labeling techniques, such as taught by Decker, would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Applicant argues that Fitzpatrick not only fails to tech the element of the present claims, but instead leads one of skilled in the art away from it. However, no explanation is provided for how Fitzpatrick teaches away from the invention. Therefore, this argument is not persuasive.

Applicant has not argued that the universal labeling system taught by Decker is different from the instant invention, therefore, it is assumed that Applicant agree that they are the same. Applicant, however, argues that the aim of the instant invention is different from that of Decker because the instant invention is not concern with multiply the antigenic reactivity in a specific immunological reaction, but to provide an element that allows the detection of analyte with a stable and reproducibly producible reagents without elaborate and expensive optimization steps. Therefore, an amplification or multiplication function of the two conjugates is not necessary in the element of the invention.

The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The argument that each hapten conjugate of Decker will have several hapten molecules bound thereto to provide amplification, and that such amplification is not necessary in the element of the invention is not persuasive. While it may be true that it is not necessary for the claimed conjugate to have several hapten molecules bound to each antibody, it is also true that the claims do not specifically exclude such a conjugate.

Applicant argues that the combination of Fitzpatrick and Decker is non-obvious because Decker does not teach the same advantage as those of the instant invention. This is not persuasive because it is well settled that if the disclosure is such as to suggest a modification or combination, such a step is obvious even if the motivation or suggestion is different from that suggested by Applicant. Furthermore, because the universal conjugate taught by Decker is the same with the conjugate of the instant invention, they would be expected to behave in the same way and thus achieve the same advantage at the least.

Applicant's arguments concerning hindsight construction are noted but not found persuasive. Contrary to applicant's position, all elements of the claimed invention are disclosed by the cited references. There is no element or part of applicant's claimed subject matter which is not suggested or specifically disclosed. The motivation to combine the teaching of these reference is found in Fitzpatrick at column 8, lines 54-57 and Decker at column 2, line 34 through column 3, line 1.

Applicant argues that Decker requires that its test sample is bound to a solid support; however, there is no explanation of why this is considered to be different from the claimed invention. Therefore, this argument is not persuasive.

Applicant argues that Bernstein fails to cure the deficiencies of Fitzpatrick and Decker because neither Fitzpatrick nor Decker, alone or in combination disclose or suggest the element of claim 15. This argument is not persuasive for reasons stated above.

Conclusion

9. No claim is allowed.

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
6/17/04